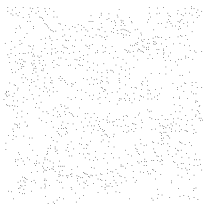
To: Wagman, Michael[Wagman.Michael@epa.gov]; Hartless, Christine[Hartless.Christine@epa.gov]; Troiano, John@CDPR[John.Troiano@cdpr.ca.gov]; Alder, Denise@CDPR[Denise.Alder@cdpr.ca.gov]; Wait, Monica[Wait.Monica@epa.gov]; Sappington, Keith[Sappington.Keith@epa.gov]; Garber, Kristina[Garber.Kristina@epa.gov]; Mroz, Ryan[Mroz.Ryan@epa.gov]; Blankinship, Amy[Blankinship.Amy@epa.gov]; Wait, Monica[Wait.Monica@epa.gov]; Corbin, Mark[Corbin.Mark@epa.gov]
Cc: Grable, Melissa[Grable.Melissa@epa.gov]; Moriarty, Thomas[Moriarty.Thomas@epa.gov]; Motilall, Christina[Motilall.Christina@epa.gov]
From: Jones, Ricardo
Sent: Thur 4/21/2016 1:04:10 PM
Subject: FW: Feedback to Clothiandin colony feeding study questions



Valent has provided partial answers to our follow-up questions on the clothianidin feeding study. I hope this helps answer any remaining questions. One of the items brought up in our joint agency meeting was missing the milestone for primary review of the feeding study, so I plan to follow up with the registrant on Monday if I haven't received more info on item #1 by then.

Ricardo

From: Shen, Sue [mailto:Sue.Shen@valent.com]
Sent: Thursday, April 21, 2016 8:16 AM
To: Jones, Ricardo <Jones.Ricardo@epa.gov>
Cc: Connor, Beth <Beth.Connor@valent.com>; jamin.huang@bayer.com; jeff.parsons@bayer.com; Moriarty, Thomas <Moriarty.Thomas@epa.gov>; tina.singal@hc-sc.gc.ca; Grable, Melissa <Grable.Melissa@epa.gov>; Denise.Alder@cdpr.ca.gov; Valent Central Files <VCF@valent.com>
Subject: RE: Feedback to Clothiandin colony feeding study questions

Ricardo :

Below are what we have so far. We are still working on item 1.

1) *Could we get exact date information for each addition/removal of the supers?*

Working on getting this data together.

2) *What were the number of frames in the supers? (we have currently assumed 10)*

Whenever an additional hive body was added, it was a deep super, had 10 frames and was placed above a queen excluder

3) *How often was the evaluation for adding a super made (i.e. just at each CCA, or at other times as well?)*

Decisions made to add or remove supers were always made during CCAs. These additions or removals would have been made either during the assessment or a few days after.

4) *What were the criteria used for determining both the addition and removal of supers?*

The decisions to add or remove a super was made during the assessments by the two beekeepers involved in the study. Supers are added when a colony has been growing and based on likely future conditions, the colony will continue to grow using up space in the hive and become more likely to swarm. The negative outcome of swarming needs to be weighed against beekeeper management of an individual hive. For the removal of supers, if a colony is not growing, but rather becoming smaller, then a super if removed if the colony is not utilizing that space. Again, the impact of individual hive management is weighed against a greater potential of negative outcomes such as small hive beetle larva gaining a foothold and sliming out a colony.

5) *When supers were added, was it just an empty hive box and frames placed on top, or was there any effort to distribute the previously utilized frames throughout the original and added hive bodies?*

When a super was added, it was a hive box with 10 new frames with foundation only (i.e., no drawn comb). At no point would a previously utilized frame be added to a hive. All frames would be added to a colony are new and foundation only. The only re-arrangement of frames within a hive would occur during the first overwintering assessment (March). This is to move the brood nest back into the lower box if a winter cluster had moved up into a super and established the brood nest in the top box. This is part of swarm prevention and all frames move and those that were originally present in that hive at that assessment.

6) *When supers were removed, did bees and/or frames of honey in the removed super get*

added back to the remaining hive bodies?

For removal of supers, there are generally very low numbers of bees or honey present if at all. The bees are relatively easily removed back into the rest of the hive. A frame with honey or nectar could be replaced with an empty frame in one of the lower boxes. Any comb that has been built on the foundation however would be removed.

Sue-Chi Shen
Regulatory Project Manager

Valent U.S.A. Corporation

Mobile (214) 784-5536 **Confidential Fax** (925) 817-5910

From: Jones, Ricardo [mailto:Jones.Ricardo@epa.gov]
Sent: Thursday, April 14, 2016 11:55 AM
To: Shen, Sue
Cc: Connor, Beth; jamin.huang@bayer.com; jeff.parsons@bayer.com; Moriarty, Thomas; tina.singal@hc-sc.gc.ca; Grable, Melissa; Denise.Alder@cdpr.ca.gov
Subject: RE: Feedback to Clothiandin colony feeding study questions

Sue,

The information provided regarding the addition of supers was very helpful, but at the same time opened up several more questions that we have in order to better inform our study evaluation and statistical approach. Could you please pass along these follow-up questions for us? Thanks.

1) Could we get exact date information for each addition/removal of the supers?

2) What were the number of frames in the supers? (we have currently assumed 10)

3) How often was the evaluation for adding a super made (*i.e.* just at each CCA, or at other times as well?)

4) What were the criteria used for determining both the addition and removal of supers?

5) When supers were added, was it just an empty hive box and frames placed on top, or was there any effort to distribute the previously utilized frames throughout the original and added hive bodies?

6) When supers were removed, did bees and/or frames of honey in the removed super get added back to the remaining hive bodies?

From: Shen, Sue [mailto:Sue.Shen@valent.com]
Sent: Thursday, April 07, 2016 10:32 AM
To: Jones, Ricardo <Jones.Ricardo@epa.gov>; tina.singal@hc-sc.gc.ca; Grable, Melissa <Grable.Melissa@epa.gov>; Denise.Alder@cdpr.ca.gov; Valent Central Files <VCF@valent.com>
Cc: Connor, Beth <Beth.Connor@valent.com>; jamin.huang@bayer.com; jeff.parsons@bayer.com
Subject: Feedback to Clothiandin colony feeding study questions

Hi, Ricardo :

Please see the attached table indicating the box number for each hive during each CCA. Please replace the previous email I sent this morning (8:02 am central time) with this one since the comments are edited slightly .

Q : To facilitate the analysis of the feeding study data, we were going to evaluate each endpoint (adults, brood, honey, etc.) as percent coverage. Assuming a 10-frame hive and the reported number of cells/frame (3970), this would be 79400 cells/hive. However, looking at the data table, this results in several hives where just honey alone has >100% coverage and including all the measurement endpoints could result in well over 100%. My best guess is that this is due to the bee's utilization of frames in the super resulting in more cells/hive than we've accounted for, though from the equations on Page 23 this doesn't quite look right. Can the registrant confirm

that this is correct or provide an alternate explanation? Also, with regards to the super, can Bayer provide the timing of super placement? (was it added to all hives at CCA3 or is there some other record for when super's were added?).

A : Supers were added and removed from individual hives as needed. The addition of supers provides space for growing colonies to expand and helps to prevent swarming. The removal of supers when they are not being used reduces the space that bees need to maintain and defend. This is especially important in preventing small hive beetles from establishing a foothold (or larval-hold) and forcing colonies out of hives. Most of the colonies were in two-box hives at the initiation of exposure.

On very rare occasions, the estimated percent coverage for a frame will add up to more than 100% for that frame. This is because sometimes, the bees draw comb perpendicular to the frames in addition to the comb found on the frame us usual (see attached picture). In these cases there are more cells associated with the frame side than usual. The coverage estimates for these frames take this additional comb into account. This happens very rarely.

Calculations used to estimate the number of bees or cells on frames are indicated in the report. It is not clear from the Agency's question what "doesn't quite look right", but we would be happy to discuss further and clarify any uncertainties. Most hives during the study contained two boxes and this is the most likely reason for having honey stores >100% coverage where 100% equals a full box (e.g., 79400 cells).

A table that indicates the number of boxes for each hive during each CCA is attached.

Q : A minor question regarding the colony feeding study data: unlike the imidacloprid data, the clothianidin data file was not presented in all integers (whole numbers), was there a reason for this? It looks like the study report did report these as integers and we were curious about why there was a difference.

A : For clothianidin, the tables in the report include numbers that were rounded to the nearest integer. The numbers in the excel spreadsheet have not been rounded.

For imidacloprid, the numbers for adult bees were rounded to the nearest integers for both the report and spreadsheet. None of the cell numbers were rounded as the calculations from frame coverage estimates resulted in whole numbers.

Different style frames were used in the two studies. For imidacloprid wooden frames with plastic foundation were

used, while for clothianidin all-plastic frames were used. While the cell sizes were the same, the number of cells on a frame were larger for the all-plastic frames. Therefore for a single box used in the clothianidin study, there were 79400 cells/box, while for the imidacloprid study, there were 68800 cells/box. This needs to be considered if one is comparing two separate studies and using percent coverage. For examples 0.2 "proportion of capped (pupal) cells" in the clothianidin is actually 15% more in total numbers than 0.2 "proportion of capped (pupal) cells" in the imidacloprid study.

Sue-Chi Shen
Regulatory Project Manager

Valent U.S.A. Corporation

Mobile (214) 784-5536 **Confidential Fax** (925) 817-5910

From: Jones, Ricardo [mailto:Jones.Ricardo@epa.gov]
Sent: Thursday, March 31, 2016 3:42 PM
To: Shen, Sue
Cc: jeff.parsons@bayer.com; Connor, Beth; jamin.huang@bayer.com; Grable, Melissa; Singal, Tina (HC/SC); Alder, Denise@CDPR
Subject: RE: Extension of clothianidin DCI study reports

Sue,

Thanks for the update, we'll let you know if we have any questions or concerns.

I also have a couple of questions for Valent from our assessment team.

1. Can you provide an updated residue matrix with the recently submitted soybean (seed) data (MRID 49803701) ahead of the report submission dates below? Along with any other new data that you can add to it, such as the corn and canola data recently generated by Bayer for clothianidin.

2. To facilitate the analysis of the feeding study data, we were going to evaluate each endpoint (adults, brood, honey, etc.) as percent coverage. Assuming a 10-frame hive and the reported number of cells/frame (3970), this would be 79400 cells/hive. However, looking at the data table, this results in several hives where just honey alone has >100% coverage and including all the measurement endpoints could result in well over 100%. My best guess is that this is due to the bee's utilization of frames in the super resulting in more cells/hive than we've accounted for, though from the equations on Page 23 this doesn't quite look right. Can the registrant confirm that this is correct or provide an alternate explanation? Also, with regards to the super, can Bayer provide the timing of super placement? (was it added to all hives at CCA3 or is there some other record for when super's were added?).

3. A minor question regarding the colony feeding study data: unlike the imidacloprid data, the clothianidin data file was not presented in all integers (whole numbers), was there a reason for this? It looks like the study report did report these as integers and we were curious about why there was a difference.

Feel free to get back to me on this next week. If you're unable to provide an updated spreadsheet before the end of the month, it would be helpful if you could provide me with a timeframe for when we can expect it.

Thanks,

Ricardo
